201-15321

Anh Nguyen
06/02/2004 12:19 PM

To: NCIC HPV@EPA
cc:
Subject: Fw: Environmental Defense comments on Sodium Dimethyldithiocarbamate (CAS# 128-04-1)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 06/02/2004 12:19 PM -----

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06/02/2004 11:28 AM

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cc: lucierg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on Sodium Dimethyldithiocarbamate (CAS# 128-04-1)

(Submitted via Internet 6/2/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and anne_lehuray@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Sodium Dimethyldithiocarbamate (CAS# 128-04-1).

The test plan and robust summaries for sodium dimethyldithiocarbamate (SDMC) were submitted by the Rubber and Plastics Additives Panel of the American Chemistry Council. SDMC is used as a water treatment chemical to precipitate heavy metal ions from water. It is also used in the rubber industry to stop the polymerization of synthetic latexes, as a registered biocide and in leather tanning and paper manufacturing. No information was provided on environmental or human exposures that might occur as a consequence of the different uses of SDMC. Its use in water treatment raises the potential concern that drinking water might contain residual SDMC. The sponsor should, in our view, provide any available data on levels in drinking water or in the general environment.

The sponsor concludes that no additional studies are needed to fulfill requirements of the HPV Program. We agree with this conclusion, with one potential exception. The test plan and robust summaries indicate that SDMC is mutagenic, based on positive results observed in several Ames tests. The sponsor states that OECD guidelines do not require in vivo mutagenicity data for SIDS endpoints. The sponsor also states that SDMC was negative in an in vitro unscheduled DNA synthesis assay, and based on this finding the sponsor concludes that SDNC is not mutagenic to mammalian cells, and proposes no additional mutagenicity testing. This is not a defensible conclusion based on the available data. It seems unwarranted that in vivo genetic toxicity data would not be generated in cases where the in vitro data were clearly positive, or even where the sponsor believes the data are ambiguous.

The sponsor indicates repeatedly in the robust summaries that some information is not being provided because it is considered confidential under FIFRA. What is the nature of the confidential information and is it toxicological in nature? If so, we find it unacceptable that toxicity information on any sponsored HPV chemical would not be supplied in fulfillment of HPV guidelines. We do not believe such health and safety information can or should be considered confidential, and that to do so is

in conflict with EPA's policies in numerous other settings. We request that EPA resolve this issue in a manner that is consistent with its other policies and in light of the fact that the Challenge program is a core element of the Agency's right-to-know initiative.

Other comments are as follows:

1. There are some inconsistencies in the robust summaries regarding the designation of NOELs and the narrative accompanying the summaries. In the repeat dose studies, a NOEL of 50 mg/kg/day is indicated. However, no information is provided on the toxic effect that was used to derive the NOEL, except to say that white blood cell and platelet counts were reduced at the high dose level. If the NOEL was derived correctly, then some effects must have been observed at the mid dose (150 mg/kg/day). Is this some of the confidential information which is not supplied?

Our concerns regarding this point are mitigated to some extent by the fact that SDMC has been tested in NCI/NTP bioassays in rats and mice, and the information from these studies is available through the NTP website. However, the repeat dose studies do not contain adequate data on methods, such as the conduct of the histological analyses, and this should be remedied in the revised test plan and robust summaries.

2. A surrogate chemical, sodium monoethyldithiocarbamate, has been used for the reproductive toxicity endpoint. This seems reasonable based on similarities in chemical structure. However, it is not clear in the test plan if the effects on the olfactory epithelium were found only in the females of the F 1 generation.

3. SDMC is highly toxic to aquatic invertebrates and algae (< 0.1 mg/L). Therefore, any data available to the sponsor on environmental releases should ideally be provided.

Thank you for this opportunity to comment.

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